

Case Series Drug Analysis Print

Name: FOI 22/1093

Report Run Date: 02-Dec-2022

Data Lock Date: 30-Nov-2022 18:30:04

Earliest Reaction Date: 13-Aug-1963

MedDRA Version: MedDRA 25.1

FOI 22/1093: All spontaneous UK reports of Dihydrocodeine up to and including 30.11.22

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Reaction Name	Total	Fatal
Blood disorders		
<i>Anaemias NEC</i>		
Anaemia	1	0
<i>Anaemias haemolytic NEC</i>		
Haemolytic anaemia	1	0
<i>Bleeding tendencies</i>		
Increased tendency to bruise	1	0
<i>Coagulopathies</i>		
Coagulopathy	1	0
<i>Eosinophilic disorders</i>		
Eosinophilia	2	0
<i>Leukopenias NEC</i>		
Leukopenia	1	0
<i>Lymphatic system disorders NEC</i>		
Lymphadenopathy	1	0
<i>Marrow depression and hypoplastic anaemias</i>		
Bone marrow failure	1	0
<i>Sickle cell trait and disorders</i>		
Sickle cell anaemia with crisis	1	0
<i>Spleen disorders</i>		
Spleen congestion	1	0
Blood disorders SOC TOTAL	11	0

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Reaction Name	Total	Fatal
Cardiac disorders		
<i>Cardiac conduction disorders</i>		
Atrioventricular block complete	2	0
<i>Cardiac disorders NEC</i>		
Cardiac disorder	1	0
Cardiovascular disorder	1	0
<i>Cardiac signs and symptoms NEC</i>		
Palpitations	10	0
<i>Coronary artery disorders NEC</i>		
Arteriosclerosis coronary artery	1	0
<i>Heart failures NEC</i>		
Cardiac failure	1	0
Cardiac failure acute	1	1
Cardiac failure congestive	1	1
Cardiopulmonary failure	1	1
Ventricular failure	1	1
<i>Ischaemic coronary artery disorders</i>		
Angina pectoris	1	0
Myocardial infarction	1	0
Myocardial ischaemia	1	0
<i>Myocardial disorders NEC</i>		
Cardiac hypertrophy	1	0
Cardiomegaly	1	0
<i>Rate and rhythm disorders NEC</i>		
Bradycardia	4	0
Cardiac flutter	1	0
Foetal heart rate deceleration abnormality	1	0
Tachycardia	7	0
<i>Supraventricular arrhythmias</i>		
Atrial fibrillation	4	0
Atrial flutter	1	0
Sinus tachycardia	1	0
<i>Ventricular arrhythmias and cardiac arrest</i>		
Cardiac arrest	2	2
Cardiac disorders SOC TOTAL	46	6

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Reaction Name	Total	Fatal
Congenital disorders		
<i>Anorectal disorders congenital</i>		
Anal atresia	1	0
<i>Cardiac septal defects congenital</i>		
Atrial septal defect	1	0
Ventricular septal defect	1	0
<i>Central nervous system disorders congenital NEC</i>		
Spina bifida occulta	1	0
<i>Congenital disorders NEC</i>		
Multiple congenital abnormalities	1	0
<i>Dental disorders congenital</i>		
Tooth hypoplasia	1	0
<i>Haematological disorders congenital NEC</i>		
Congenital thrombocytopenia	1	0
<i>Musculoskeletal and connective tissue disorders of limbs congenital</i>		
Congenital musculoskeletal disorder of limbs	2	0
Developmental hip dysplasia	1	0
Poland's syndrome	1	0
Talipes	1	0
<i>Musculoskeletal and connective tissue disorders of spine congenital</i>		
Congenital musculoskeletal disorder of spine	1	0
<i>Musculoskeletal disorders congenital NEC</i>		
Congenital multiplex arthrogryposis	1	0
<i>Neurological disorders congenital NEC</i>		
Congenital nystagmus	3	0
<i>Ocular disorders congenital NEC</i>		
Congenital visual acuity reduced	1	0
Strabismus congenital	1	0
<i>Renal and urinary tract disorders congenital NEC</i>		
Urinary tract malformation	1	0
Congenital disorders SOC TOTAL	20	0

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Reaction Name	Total	Fatal
Ear disorders		
<i>Ear disorders NEC</i>		
Ear pain	1	0
Otorrhoea	1	0
<i>Hearing losses</i>		
Deafness bilateral	1	0
Deafness neurosensory	1	0
Hypoacusis	1	0
<i>Inner ear signs and symptoms</i>		
Tinnitus	4	0
Vertigo	26	0
Ear disorders SOC TOTAL	35	0

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Reaction Name	Total	Fatal
Endocrine disorders		
<i>Adrenal cortical hypofunctions</i>		
Adrenal insufficiency	2	0
<i>Endocrine abnormalities of gonadal function NEC</i>		
Hypogonadism	1	0
<i>Hypothalamic and pituitary disorders NEC</i>		
Secondary hypogonadism	2	0
<i>Posterior pituitary disorders</i>		
Inappropriate antidiuretic hormone secretion	3	0
Endocrine disorders SOC TOTAL	8	0

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Reaction Name	Total	Fatal
Eye disorders		
<i>Choroid and vitreous structural change, deposit and degeneration</i>		
Vitreous floaters	1	0
<i>Conjunctival infections, irritations and inflammations</i>		
Conjunctival hyperaemia	1	0
<i>Eyelid movement disorders</i>		
Blepharospasm	2	0
<i>Lacrimation disorders</i>		
Dry eye	1	0
Lacrimation increased	1	0
<i>Lid, lash and lacrimal infections, irritations and inflammations</i>		
Swelling of eyelid	1	0
<i>Ocular bleeding and vascular disorders NEC</i>		
Eye haemorrhage	1	0
<i>Ocular disorders NEC</i>		
Eye pain	1	0
Eye swelling	4	0
Ocular discomfort	1	0
Periorbital oedema	1	0
<i>Ocular infections, inflammations and associated manifestations</i>		
Eye discharge	1	0
Eye pruritus	3	0
<i>Ocular sensation disorders</i>		
Foreign body sensation in eyes	1	0
<i>Optic disc abnormalities NEC</i>		
Optic atrophy	1	0
<i>Pupil disorders</i>		
Miosis	2	0
<i>Refractive and accommodative disorders</i>		
Accommodation disorder	1	0
Hypermetropia	1	0
<i>Visual disorders NEC</i>		
Diplopia	5	0
Vision blurred	6	0
<i>Visual field disorders</i>		
Visual field defect	2	0
<i>Visual impairment and blindness (excl colour blindness)</i>		
Blindness	1	0
Visual acuity reduced	1	0
Visual impairment	9	0
Eye disorders SOC TOTAL	49	0

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Reaction Name	Total	Fatal
Gastrointestinal disorders		
<i>Acute and chronic pancreatitis</i>		
Pancreatitis	2	0
Pancreatitis acute	3	0
<i>Colitis (excl infective)</i>		
Colitis	2	0
<i>Dental disorders NEC</i>		
Tooth disorder	1	0
<i>Diarrhoea (excl infective)</i>		
Diarrhoea	32	0
<i>Duodenal and small intestinal stenosis and obstruction</i>		
Small intestinal obstruction	1	0
<i>Duodenal ulcers and perforation</i>		
Duodenal ulcer haemorrhage	1	0
Erosive duodenitis	5	0
<i>Dyspeptic signs and symptoms</i>		
Dyspepsia	7	0
<i>Faecal abnormalities NEC</i>		
Faecaloma	2	0
Faeces pale	1	0
<i>Flatulence, bloating and distension</i>		
Abdominal distension	6	0
<i>Gastric ulcers and perforation</i>		
Gastric ulcer	3	0
<i>Gastritis (excl infective)</i>		
Gastritis	3	0
<i>Gastrointestinal and abdominal pains (excl oral and throat)</i>		
Abdominal pain	42	0
Abdominal pain lower	3	0
Abdominal pain upper	28	0
Abdominal rigidity	2	0
Abdominal tenderness	4	0
Gastrointestinal pain	3	0
<i>Gastrointestinal atonic and hypomotility disorders NEC</i>		
Constipation	78	0
Gastric dilatation	1	0
Gastrointestinal hypomotility	1	0
Gastrooesophageal reflux disease	2	0
<i>Gastrointestinal disorders NEC</i>		
Functional gastrointestinal disorder	1	0
Gastric disorder	1	0
Pneumatosis intestinalis	1	0
<i>Gastrointestinal dyskinetic disorders</i>		
Change of bowel habit	1	0
Gastrointestinal motility disorder	1	0
<i>Gastrointestinal inflammatory disorders NEC</i>		
Enteritis	1	0
Enterocolitis	1	0
<i>Gastrointestinal signs and symptoms NEC</i>		
Abdominal discomfort	1	0
Dysphagia	7	0
<i>Gastrointestinal spastic and hypermotility disorders</i>		
Defaecation urgency	1	0
<i>Gastrointestinal stenosis and obstruction NEC</i>		

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Reaction Name	Total	Fatal
Gastrointestinal disorders		
Gastrointestinal disorders cont'd		
Intestinal obstruction	2	1
Gingival disorders, signs and symptoms NEC		
Gingival swelling	1	0
Inguinal hernias		
Inguinal hernia	1	0
Intestinal haemorrhages		
Rectal haemorrhage	2	0
Intestinal ulcers and perforation NEC		
Intestinal perforation	1	0
Intestinal ulcer	1	0
Large intestinal ulcer	3	0
Large intestine perforation	5	0
Malabsorption syndromes		
Malabsorption	1	0
Nausea and vomiting symptoms		
Nausea	160	0
Retching	2	0
Vomiting	182	0
Non-site specific gastrointestinal haemorrhages		
Gastrointestinal haemorrhage	4	2
Haematemesis	5	0
Haematochezia	2	0
Melaena	7	0
Upper gastrointestinal haemorrhage	2	0
Oesophageal ulcers and perforation		
Oesophageal ulcer	1	0
Oesophagitis (excl infective)		
Oesophagitis	6	0
Oral dryness and saliva altered		
Dry mouth	23	0
Oral soft tissue disorders NEC		
Oral lichen planus	1	0
Oral soft tissue signs and symptoms		
Hypoaesthesia oral	2	0
Oral discomfort	1	0
Paraesthesia oral	1	0
Oral soft tissue swelling and oedema		
Lip swelling	12	0
Mouth swelling	4	0
Peritoneal and retroperitoneal disorders		
Pneumoperitoneum	1	0
Stomatitis and ulceration		
Mouth ulceration	5	0
Tongue disorders		
Tongue ulceration	1	0
Tongue signs and symptoms		
Swollen tongue	5	0
Tongue discolouration	1	0
Tongue discomfort	1	0
Tongue oedema	2	0
Gastrointestinal disorders SOC TOTAL	697	3

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Reaction Name	Total	Fatal
General disorders		
<i>Asthenic conditions</i>		
Asthenia	15	0
Fatigue	19	0
Malaise	43	0
<i>Body temperature altered</i>		
Hypothermia	1	1
<i>Death and sudden death</i>		
Death	8	6
Sudden unexplained death in epilepsy	1	1
<i>Febrile disorders</i>		
Hyperpyrexia	1	0
Pyrexia	13	0
<i>Feelings and sensations NEC</i>		
Chills	12	0
Feeling abnormal	17	0
Feeling drunk	1	0
Feeling hot	7	0
Feeling jittery	1	0
Sensation of foreign body	1	0
Temperature intolerance	1	0
Thirst	2	0
<i>Gait disturbances</i>		
Gait disturbance	3	0
Gait inability	1	0
<i>General signs and symptoms NEC</i>		
Adhesion	1	0
Condition aggravated	5	0
Crying	3	0
Developmental delay	1	0
Disease recurrence	1	0
General physical health deterioration	1	0
Illness	18	0
Impaired self-care	1	0
Influenza like illness	2	0
Multiple organ dysfunction syndrome	2	0
Peripheral swelling	5	0
Screaming	1	0
Swelling	2	0
Swelling face	10	0
<i>Hernias NEC</i>		
Hernia	1	0
<i>Implant and catheter site reactions</i>		
Implant site extravasation	1	0
<i>Inflammations</i>		
Granuloma	1	0
Inflammation	3	0
<i>Injection site reactions</i>		
Injection site haemorrhage	1	0
Injection site pain	1	0
Injection site reaction	3	0
<i>Interactions</i>		
Alcohol interaction	1	0
Drug interaction	29	0

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General disorders General disorders cont'd		
Inhibitory drug interaction	6	0
Potentiating drug interaction	3	0
Oedema NEC		
Face oedema	8	0
Generalised oedema	2	0
Oedema	8	0
Oedema peripheral	9	0
Pain and discomfort NEC		
Chest discomfort	2	0
Chest pain	21	0
Discomfort	4	0
Pain	28	0
Tenderness	1	0
Therapeutic and nontherapeutic responses		
Adverse drug reaction	10	0
Drug ineffective	16	0
Drug intolerance	2	0
Drug tolerance	3	0
Drug tolerance increased	1	0
Inadequate analgesia	2	0
Therapeutic product effect decreased	1	0
Therapeutic response decreased	1	0
Therapeutic response unexpected	1	0
Treatment failure	1	0
Withdrawal and rebound effects		
Drug withdrawal syndrome	20	0
Drug withdrawal syndrome neonatal	4	0
Withdrawal syndrome	24	0
General disorders SOC TOTAL	419	8

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Hepatic disorders		
<i>Bile duct infections and inflammations</i>		
Biliary colic	2	0
<i>Cholestasis and jaundice</i>		
Cholestasis of pregnancy	3	0
Jaundice	4	0
Jaundice cholestatic	1	0
<i>Hepatic and hepatobiliary disorders NEC</i>		
Liver disorder	1	0
<i>Hepatic enzymes and function abnormalities</i>		
Hepatic function abnormal	5	0
<i>Hepatic failure and associated disorders</i>		
Acute hepatic failure	1	0
<i>Hepatobiliary signs and symptoms</i>		
Hepatic pain	2	0
Hepatomegaly	1	0
<i>Hepatocellular damage and hepatitis NEC</i>		
Hepatic necrosis	2	1
Hepatic steatosis	3	0
Hepatitis	3	0
Hepatotoxicity	1	0
<i>Obstructive bile duct disorders (excl neoplasms)</i>		
Sphincter of Oddi dysfunction	1	0
Hepatic disorders SOC TOTAL	30	1

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Reaction Name	Total	Fatal
Immune system disorders		
<i>Allergic conditions NEC</i>		
Hypersensitivity	15	0
<i>Allergies to foods, food additives, drugs and other chemicals</i>		
Drug hypersensitivity	6	0
<i>Anaphylactic and anaphylactoid responses</i>		
Anaphylactic reaction	12	0
Anaphylactic shock	1	0
Anaphylactoid reaction	3	0
Immune system disorders SOC TOTAL	37	0

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Reaction Name	Total	Fatal
Infections		
<i>Abdominal and gastrointestinal infections</i>		
Diverticulitis	1	0
<i>Breast infections</i>		
Breast abscess	2	0
<i>Candida infections</i>		
Oral candidiasis	2	0
<i>Clostridia infections</i>		
Clostridial infection	1	1
<i>Eye and eyelid infections</i>		
Conjunctivitis	1	0
Eye infection	1	0
<i>Fungal infections NEC</i>		
Onychomycosis	1	0
<i>Herpes viral infections</i>		
Oral herpes	1	0
<i>Infections NEC</i>		
Empyema	1	0
Implant site infection	1	0
Infection	1	0
Purulent discharge	1	0
Wound infection	1	0
<i>Lower respiratory tract and lung infections</i>		
Lower respiratory tract infection	2	0
Pneumonia	4	2
Pneumonia aspiration	5	1
<i>Muscle and soft tissue infections</i>		
Necrotising fasciitis	1	0
<i>Retroviral infections</i>		
Acquired immunodeficiency syndrome	1	0
<i>Sepsis, bacteraemia, viraemia and fungaemia NEC</i>		
Sepsis	4	3
Sepsis neonatal	1	0
<i>Staphylococcal infections</i>		
Furuncle	3	0
<i>Upper respiratory tract infections</i>		
Rhinitis	1	0
<i>Urinary tract infections</i>		
Urinary tract infection	4	0
Infections SOC TOTAL	41	7

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Reaction Name	Total	Fatal
Injuries		
<i>Accidental exposures to product</i>		
Accidental exposure to product	1	0
<i>Anaesthetic and allied procedural complications</i>		
Sedation complication	1	0
<i>Cerebral injuries NEC</i>		
Subdural haematoma	1	1
<i>Chest and respiratory tract injuries NEC</i>		
Chest injury	1	0
<i>Exposures associated with pregnancy, delivery and lactation</i>		
Exposure during pregnancy	5	0
Exposure via breast milk	1	0
Foetal exposure during pregnancy	6	0
Maternal exposure during breast feeding	1	0
Maternal exposure during pregnancy	5	0
<i>Intentional product misuses</i>		
Intentional product misuse	12	0
<i>Intentional product use issues</i>		
Intentional product use issue	1	0
<i>Medication errors, product use errors and issues NEC</i>		
Circumstance or information capable of leading to medication error	1	0
Prescription drug used without a prescription	3	0
Product use in unapproved indication	2	0
Wrong technique in product usage process	1	0
<i>Muscle, tendon and ligament injuries</i>		
Muscle injury	1	0
<i>Non-site specific injuries NEC</i>		
Accident at home	1	0
Fall	13	1
Injury	1	0
<i>Non-site specific procedural complications</i>		
Wound dehiscence	1	0
<i>Off label uses</i>		
Off label use	3	0
<i>Overdoses NEC</i>		
Intentional overdose	18	1
Overdose	54	10
<i>Poisoning and toxicity</i>		
Accidental poisoning	1	1
Alcohol poisoning	3	1
Carbon monoxide poisoning	1	0
Toxicity to various agents	55	41
<i>Product administration errors and issues</i>		
Accidental overdose	5	1
Expired product administered	1	0
Inappropriate schedule of product administration	1	0
Incorrect dose administered	2	0
Incorrect dose administered by product	1	0
Incorrect product dosage form administered	1	0
Wrong product administered	1	0
<i>Product confusion errors and issues</i>		
Product packaging confusion	1	0
<i>Product dispensing errors and issues</i>		
Product dispensing error	6	0

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Reaction Name	Total	Fatal
Injuries Injuries cont'd		
<i>Product monitoring errors and issues</i>		
Documented hypersensitivity to administered product	1	0
<i>Site specific injuries NEC</i>		
Limb injury	1	0
<i>Skin injuries NEC</i>		
Contusion	3	0
Scar	1	0
Scratch	1	0
Skin abrasion	1	0
Injuries SOC TOTAL	221	57

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Reaction Name	Total	Fatal
Investigations		
<i>Blood gas and acid base analyses</i>		
Blood bicarbonate decreased	1	0
Blood lactic acid increased	1	0
Oxygen saturation decreased	1	0
pH body fluid decreased	1	0
<i>Carbohydrate tolerance analyses (incl diabetes)</i>		
Blood glucose decreased	1	0
<i>Chemistry analyses NEC</i>		
Serum serotonin increased	1	0
<i>Coagulation and bleeding analyses</i>		
Fibrinolysis increased	1	0
International normalised ratio	1	0
International normalised ratio increased	3	0
<i>ECG investigations</i>		
Electrocardiogram QT prolonged	1	0
<i>Faecal analyses NEC</i>		
Occult blood positive	1	0
<i>Foetal and neonatal diagnostic procedures</i>		
Foetal monitoring abnormal	1	0
<i>Haematological analyses NEC</i>		
Red blood cell sedimentation rate increased	1	0
<i>Heart rate and pulse investigations</i>		
Heart rate decreased	2	0
Heart rate increased	8	0
<i>Hepatobiliary function diagnostic procedures</i>		
Alanine aminotransferase increased	1	0
Aspartate aminotransferase increased	1	0
Blood bilirubin increased	1	0
Gamma-glutamyltransferase abnormal	1	0
Liver function test abnormal	3	0
Liver function test increased	3	0
<i>Investigations NEC</i>		
Quality of life decreased	1	0
<i>Mineral and electrolyte analyses</i>		
Blood calcium decreased	1	0
Blood iron increased	1	0
Blood phosphorus decreased	1	0
Serum ferritin increased	1	0
Urine sodium increased	1	0
<i>Neurologic diagnostic procedures</i>		
Coma scale abnormal	4	0
<i>Physical examination procedures and organ system status</i>		
Body temperature decreased	1	0
Body temperature increased	1	0
Respiratory rate decreased	4	0
Weight decreased	2	0
Weight increased	1	0
<i>Platelet analyses</i>		
Platelet count decreased	2	0
Platelet function test abnormal	4	0
<i>Protein analyses NEC</i>		
C-reactive protein increased	2	0
<i>Red blood cell analyses</i>		

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Investigations Investigations cont'd		
Haemoglobin decreased	8	0
Renal function analyses		
Blood creatine increased	1	0
Blood creatinine increased	2	0
Blood urea increased	1	0
Renal function test abnormal	1	0
Respiratory tract and thoracic histopathology procedures		
Bronchial aspiration procedure	1	0
Skeletal and cardiac muscle analyses		
Blood creatine phosphokinase increased	1	0
Therapeutic drug monitoring analyses		
Analgesic drug level increased	1	0
Antipsychotic drug level increased	1	0
Thyroid analyses		
Thyroxine increased	1	0
Toxicology laboratory analyses		
Blood ethanol increased	1	0
Drug screen positive	2	0
Urinalysis NEC		
Blood urine present	1	0
Urine analysis abnormal	3	0
Vascular tests NEC (incl blood pressure)		
Blood pressure decreased	2	0
Blood pressure diastolic decreased	1	0
Blood pressure increased	2	0
Water and electrolyte analyses NEC		
Blood osmolarity decreased	1	0
Urine osmolarity increased	1	0
White blood cell analyses		
Macrophages increased	1	0
Neutrophil count increased	1	0
White blood cell count increased	1	0
Investigations SOC TOTAL	97	0

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Metabolic disorders		
<i>Appetite disorders</i>		
Decreased appetite	17	0
<i>Calcium metabolism disorders</i>		
Hypocalcaemia	1	0
<i>Diabetes mellitus (incl subtypes)</i>		
Diabetes mellitus	1	0
<i>Diabetic complications NEC</i>		
Diabetic ketoacidosis	1	0
<i>Electrolyte imbalance NEC</i>		
Electrolyte imbalance	1	0
<i>Food malabsorption and intolerance syndromes (excl sugar intolerance)</i>		
Dairy intolerance	1	0
Feeding intolerance	1	0
<i>General nutritional disorders NEC</i>		
Abnormal loss of weight	2	0
Feeding disorder	2	0
<i>Hypoglycaemic conditions NEC</i>		
Hypoglycaemia	1	0
Hypoglycaemia neonatal	1	0
<i>Metabolic acidoses (excl diabetic acidoses)</i>		
Metabolic acidosis	1	0
<i>Potassium imbalance</i>		
Hyperkalaemia	2	0
<i>Sodium imbalance</i>		
Hyponatraemia	1	0
<i>Sugar intolerance (excl glucose intolerance)</i>		
Lactose intolerance	1	0
<i>Total fluid volume decreased</i>		
Dehydration	2	0
Metabolic disorders SOC TOTAL	36	0

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Reaction Name	Total	Fatal
Muscle & tissue disorders		
<i>Joint related signs and symptoms</i>		
Arthralgia	5	0
Joint swelling	1	0
<i>Muscle infections and inflammations</i>		
Polymyositis	1	0
<i>Muscle pains</i>		
Myalgia	5	0
<i>Muscle related signs and symptoms NEC</i>		
Muscle atrophy	1	0
Muscle spasms	7	0
Muscle twitching	3	0
<i>Muscle tone abnormalities</i>		
Muscle rigidity	1	0
Torticollis	1	0
<i>Muscle weakness conditions</i>		
Muscular weakness	5	0
<i>Musculoskeletal and connective tissue conditions NEC</i>		
Mobility decreased	2	0
Musculoskeletal stiffness	3	0
Posture abnormal	1	0
<i>Musculoskeletal and connective tissue pain and discomfort</i>		
Back pain	6	0
Pain in extremity	5	0
<i>Myopathies</i>		
Myopathy	1	0
Rhabdomyolysis	4	0
<i>Osteoarthropathies</i>		
Osteoarthritis	3	0
<i>Rheumatoid arthropathies</i>		
Rheumatoid arthritis	1	0
Muscle & tissue disorders SOC TOTAL	56	0

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Reaction Name	Total	Fatal
Neoplasms		
<i>Cardiovascular neoplasms benign</i>		
Cardiac fibroma	1	0
<i>Neoplasms malignant site unspecified NEC</i>		
Neoplasm malignant	1	0
Neoplasms SOC TOTAL	2	0

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Autonomic nervous system disorders</i>		
Horner's syndrome	1	0
<i>Central nervous system haemorrhages and cerebrovascular accidents</i>		
Cerebellar stroke	1	0
Cerebral infarction	1	0
Haemorrhage intracranial	1	0
Ischaemic stroke	1	0
<i>Choreiform movements</i>		
Choreoathetosis	1	0
<i>Coma states</i>		
Coma	16	0
<i>Coordination and balance disturbances</i>		
Ataxia	6	0
Balance disorder	6	0
Dysstasia	1	0
Nystagmus	2	0
<i>Cortical dysfunction NEC</i>		
Aphasia	1	0
<i>Disturbances in consciousness NEC</i>		
Depressed level of consciousness	7	0
Lethargy	12	0
Loss of consciousness	11	0
Sedation	7	0
Somnolence	59	0
Stupor	9	0
Syncope	35	0
<i>Dyskinesias and movement disorders NEC</i>		
Akathisia	2	0
Dyskinesia	1	0
Extrapyramidal disorder	2	0
Hyperkinesia	5	0
<i>Dystonias</i>		
Dystonia	1	0
<i>Facial cranial nerve disorders</i>		
Facial paralysis	2	0
<i>Generalised tonic-clonic seizures</i>		
Generalised tonic-clonic seizure	4	0
<i>Headaches NEC</i>		
Headache	60	0
Medication overuse headache	1	0
<i>Increased intracranial pressure disorders</i>		
Brain oedema	1	0
<i>Lumbar spinal cord and nerve root disorders</i>		
Sciatica	1	0
<i>Memory loss (excl dementia)</i>		
Amnesia	4	0
Memory impairment	6	0
<i>Mental impairment (excl dementia and memory loss)</i>		
Cognitive disorder	3	0
Disturbance in attention	5	0
Judgement impaired	2	0
Mental impairment	1	0
<i>Migraine headaches</i>		

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Reaction Name	Total	Fatal
Nervous system disorders		
Nervous system disorders cont'd		
Migraine	5	0
Mononeuropathies		
Carpal tunnel syndrome	1	0
Femoral nerve palsy	1	0
Muscle tone abnormal		
Hypotonia	1	0
Serotonin syndrome	2	0
Narcolepsy and hypersomnia		
Hypersomnia	1	0
Neurological signs and symptoms NEC		
Dizziness	147	0
Dizziness postural	3	0
Drooling	1	0
Head discomfort	2	0
Myoclonus	2	0
Patient elopement	1	0
Presyncope	2	0
Neuromuscular disorders NEC		
Muscle spasticity	1	0
Olfactory nerve disorders		
Anosmia	1	0
Paraesthesias and dysaesthesias		
Burning feet syndrome	1	0
Burning sensation	2	0
Dysaesthesia	1	0
Formication	2	0
Hyperaesthesia	1	0
Hypoaesthesia	6	0
Paraesthesia	19	0
Paralysis and paresis (excl cranial nerve)		
Diplegia	1	0
Hemiplegia	1	0
Paralysis	1	0
Peripheral neuropathies NEC		
Neuropathy peripheral	2	0
Polyneuropathy	1	0
Seizures and seizure disorders NEC		
Epilepsy	5	0
Seizure	13	0
Sensory abnormalities NEC		
Allodynia	1	0
Dysgeusia	1	0
Electric shock sensation	3	0
Restless legs syndrome	1	0
Sensory disturbance	2	0
Taste disorder	1	0
Speech and language abnormalities		
Dysarthria	4	0
Speech disorder	1	0
Tremor (excl congenital)		
Tremor	27	0
Nervous system disorders SOC TOTAL	547	0

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Reaction Name	Total	Fatal
Pregnancy conditions		
<i>Abortions spontaneous</i>		
Abortion spontaneous	1	0
<i>Foetal growth complications</i>		
Foetal growth restriction	1	0
<i>Gestational age and weight conditions</i>		
Low birth weight baby	1	0
Premature baby	3	0
<i>Haemorrhagic complications of pregnancy</i>		
Premature separation of placenta	1	0
<i>Hypertension associated disorders of pregnancy</i>		
Pre-eclampsia	1	0
<i>Labour onset and length abnormalities</i>		
Premature labour	3	0
<i>Normal pregnancy, labour and delivery</i>		
Live birth	3	0
<i>Unintended pregnancies</i>		
Unintended pregnancy	1	0
Pregnancy conditions SOC TOTAL	15	0

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Reaction Name	Total	Fatal
<i>Device physical property and chemical issues</i>		
Syringe issue	1	0
<i>Product packaging issues</i>		
Product blister packaging issue	1	0
<i>Product physical issues</i>		
Product physical issue	1	0
Product taste abnormal	1	0
<i>Product quality issues NEC</i>		
Product quality issue	1	0
Product substitution issue	4	0
<i>Product supply and availability issues</i>		
Product availability issue	1	0
Product supply issue	2	0
null SOC TOTAL	12	0

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Reaction Name	Total	Fatal
Psychiatric disorders		
<i>Abnormal behaviour NEC</i>		
Abnormal behaviour	4	0
Behaviour disorder	1	0
<i>Affect alterations NEC</i>		
Flat affect	1	0
Inappropriate affect	1	0
<i>Anxiety symptoms</i>		
Agitation	10	0
Anxiety	20	0
Stress	2	0
Tension	1	0
<i>Behaviour and socialisation disturbances</i>		
Aggression	6	0
Disturbance in social behaviour	2	0
Paranoia	2	0
Personality change	2	0
Social avoidant behaviour	1	0
<i>Confusion and disorientation</i>		
Confusional state	43	0
Disorientation	14	0
<i>Deliria</i>		
Delirium	3	0
<i>Delusional symptoms</i>		
Delusion	2	0
<i>Depressive disorders</i>		
Depression	14	0
<i>Dissociative states</i>		
Depersonalisation/derealisation disorder	5	0
<i>Disturbances in initiating and maintaining sleep</i>		
Insomnia	26	0
<i>Eating disorders NEC</i>		
Anorexia nervosa	1	1
Eating disorder	1	0
<i>Emotional and mood disturbances NEC</i>		
Anger	2	0
Dysphoria	1	0
Emotional distress	2	0
Euphoric mood	6	0
Irritability	4	0
Mood altered	2	0
<i>Fear symptoms and phobic disorders (incl social phobia)</i>		
Fear	2	0
<i>Fluctuating mood symptoms</i>		
Mood swings	6	0
<i>Hallucinations (excl sleep-related)</i>		
Hallucination	42	0
Hallucination, auditory	3	0
Hallucination, visual	2	0
Hallucinations, mixed	3	0
<i>Impulse control disorders</i>		
Impulse-control disorder	1	0
Impulsive behaviour	2	0
<i>Increased physical activity levels</i>		

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Reaction Name	Total	Fatal
Psychiatric disorders ^{Psychiatric disorders cont'd}		
Restlessness	5	0
Learning disorders		
Learning disorder	1	0
Mental disorders NEC		
Mental disorder	5	0
Mental status changes	1	0
Mood alterations with depressive symptoms		
Decreased interest	1	0
Depressed mood	11	0
Feeling of despair	1	0
Tearfulness	1	0
Mood disorders NEC		
Apathy	3	0
Obsessive-compulsive disorders and symptoms		
Compulsions	1	0
Obsessive thoughts	1	0
Panic attacks and disorders		
Panic attack	5	0
Parasomnias		
Abnormal dreams	3	0
Nightmare	5	0
Rapid eye movements sleep abnormal	1	0
Perception disturbances NEC		
Autoscopy	2	0
Derealisation	1	0
Illusion	1	0
Psychiatric symptoms NEC		
Psychiatric symptom	1	0
Psychotic disorder NEC		
Acute psychosis	1	0
Psychotic disorder	6	0
Schizoaffective and schizophreniform disorders		
Schizoaffective disorder	1	0
Sexual desire disorders		
Hypersexuality	1	0
Libido decreased	1	0
Libido increased	1	0
Sexual dysfunction NEC		
Genito-pelvic pain/penetration disorder	1	0
Sleep disorders NEC		
Sleep disorder	2	0
Substance related and addictive disorders		
Alcoholism	1	0
Dependence	9	0
Drug abuse	19	0
Drug dependence	138	0
Substance abuse	2	0
Suicidal and self-injurious behaviour		
Completed suicide	4	4
Intentional self-injury	3	0
Suicidal ideation	6	0
Suicide attempt	1	0
Thinking disturbances		

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Reaction Name	Total	Fatal
Psychiatric disorders Psychiatric disorders cont'd		
Thinking abnormal	2	0
Psychiatric disorders SOC TOTAL	489	5

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Reaction Name	Total	Fatal
Renal & urinary disorders		
<i>Bladder and urethral symptoms</i>		
Bladder pain	1	0
Dysuria	7	0
Incontinence	1	0
Micturition disorder	4	0
Pollakiuria	2	0
Urinary incontinence	2	0
Urinary retention	15	0
Urine flow decreased	1	0
<i>Genital and urinary tract disorders NEC</i>		
Urinary tract disorder	1	0
<i>Nephritis NEC</i>		
Tubulointerstitial nephritis	1	0
<i>Nephropathies and tubular disorders NEC</i>		
Nephrosclerosis	1	0
<i>Renal disorders NEC</i>		
Renal disorder	3	0
<i>Renal failure and impairment</i>		
Acute kidney injury	8	0
Chronic kidney disease	1	0
Oliguria	1	0
Renal failure	3	0
Renal impairment	1	0
<i>Renal neoplasms</i>		
Renal cyst	2	0
<i>Urinary abnormalities</i>		
Chromaturia	3	0
Renal & urinary disorders SOC TOTAL	58	0

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Reaction Name	Total	Fatal
Reproductive & breast disorders		
<i>Breast disorders NEC</i>		
Breast enlargement	1	0
<i>Erection and ejaculation conditions and disorders</i>		
Ejaculation failure	1	0
Erectile dysfunction	8	0
Erection increased	1	0
Priapism	3	0
<i>Lactation disorders</i>		
Galactorrhoea	1	0
<i>Menstruation with decreased bleeding</i>		
Amenorrhoea	3	0
Oligomenorrhoea	2	0
<i>Menstruation with increased bleeding</i>		
Heavy menstrual bleeding	1	0
<i>Prostatic neoplasms and hypertrophy</i>		
Benign prostatic hyperplasia	1	0
<i>Sexual function and fertility disorders NEC</i>		
Dyspareunia	1	0
Sexual dysfunction	1	0
<i>Testicular and epididymal disorders NEC</i>		
Testicular pain	1	0
<i>Uterine disorders NEC</i>		
Endometriosis	1	0
Reproductive & breast disorders SOC TOTAL	26	0

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Reaction Name	Total	Fatal
Respiratory disorders		
<i>Breathing abnormalities</i>		
Apnoea	1	0
Dyspnoea	24	0
Dyspnoea at rest	1	0
Hyperventilation	1	0
Respiratory arrest	2	0
Respiratory depression	21	3
Sleep apnoea syndrome	1	0
<i>Bronchospasm and obstruction</i>		
Asthma	4	0
Bronchospasm	6	0
Wheezing	3	0
<i>Conditions associated with abnormal gas exchange</i>		
Respiratory gas exchange disorder	1	0
<i>Coughing and associated symptoms</i>		
Cough	6	0
Haemoptysis	1	0
<i>Laryngeal spasm, oedema and obstruction</i>		
Epiglottic oedema	1	0
Laryngeal oedema	2	0
<i>Lower respiratory tract inflammatory and immunologic conditions</i>		
Pneumonitis aspiration	2	1
<i>Lower respiratory tract signs and symptoms</i>		
Hiccups	4	0
<i>Nasal disorders NEC</i>		
Epistaxis	5	0
<i>Neonatal hypoxic conditions</i>		
Infantile apnoea	1	0
Neonatal respiratory distress syndrome	1	0
<i>Parenchymal lung disorders NEC</i>		
Interstitial lung disease	1	0
Lung infiltration	1	0
<i>Pharyngeal disorders (excl infections and neoplasms)</i>		
Pharyngeal disorder	1	0
Pharyngeal oedema	1	0
Pharyngeal swelling	2	0
<i>Pneumothorax and pleural effusions NEC</i>		
Haemothorax	1	0
Pneumothorax	1	0
<i>Pulmonary oedemas</i>		
Pulmonary congestion	2	0
Pulmonary oedema	4	0
<i>Pulmonary thrombotic and embolic conditions</i>		
Pulmonary embolism	1	1
<i>Respiratory failures (excl neonatal)</i>		
Respiratory failure	6	1
<i>Respiratory tract disorders NEC</i>		
Aspiration	1	1
<i>Upper respiratory tract signs and symptoms</i>		
Choking	2	1
Dry throat	1	0
Dysphonia	2	0
Laryngeal pain	1	0

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Reaction Name	Total	Fatal
Respiratory disorders Respiratory disorders cont'd		
Oropharyngeal pain	3	0
Rhinorrhoea	1	0
Sneezing	1	0
Snoring	1	0
Throat tightness	1	0
Yawning	1	0
Vascular pulmonary disorders NEC		
Acute chest syndrome	1	1
Respiratory disorders SOC TOTAL	125	9

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Reaction Name	Total	Fatal
Skin disorders		
Acnes		
Acne	1	0
Alopecias		
Alopecia	4	0
Angioedemas		
Angioedema	10	0
Apocrine and eccrine gland disorders		
Cold sweat	6	0
Hyperhidrosis	37	0
Night sweats	1	0
Bullous conditions		
Blister	4	0
Dermatitis bullous	1	0
Erythema multiforme	4	0
Stevens-Johnson syndrome	1	0
Toxic epidermal necrolysis	2	0
Dermal and epidermal conditions NEC		
Dry skin	1	0
Pain of skin	1	0
Skin burning sensation	2	0
Skin disorder	1	0
Skin necrosis	1	0
Skin warm	1	0
Dermatitis and eczema		
Dermatitis allergic	6	0
Eczema	1	0
Skin irritation	2	0
Dermatitis ascribed to specific agent		
Fixed eruption	1	0
Erythemas		
Erythema	11	0
Exfoliative conditions		
Dermatitis exfoliative	5	0
Dermatitis exfoliative generalised	1	0
Skin exfoliation	5	0
Panniculitides		
Erythema nodosum	2	0
Photosensitivity and photodermatosis conditions		
Photosensitivity reaction	6	0
Pruritus NEC		
Pruritus	103	0
Purpura and related conditions		
Petechiae	5	0
Purpura	6	0
Pustular conditions		
Acute generalised exanthematous pustulosis	1	0
Rash follicular	1	0
Rashes, eruptions and exanthems NEC		
Rash	64	0
Rash erythematous	23	0
Rash macular	3	0
Rash maculo-papular	18	0
Rash morbilliform	3	0

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Reaction Name	Total	Fatal
Skin disorders Skin disorders cont'd		
Rash pruritic	7	0
Rash vesicular	1	0
<i>Skin and subcutaneous tissue ulcerations</i>		
Skin ulcer	1	0
<i>Skin vasculitides</i>		
Vasculitic rash	1	0
<i>Urticarias</i>		
Urticaria	45	0
Skin disorders SOC TOTAL	400	0

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Reaction Name	Total	Fatal
Social circumstances		
<i>Crime victims</i>		
Victim of abuse	1	0
<i>Criminal activity</i>		
Drug diversion	5	0
Legal problem	1	0
<i>Disability issues</i>		
Immobile	1	0
Loss of personal independence in daily activities	2	0
<i>Drug and chemical abuse</i>		
Drug abuser	1	0
<i>Social issues NEC</i>		
Social problem	1	0
Substance use	1	0
Social circumstances SOC TOTAL	13	0

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Reaction Name	Total	Fatal
Surgical & medical procedures		
<i>Therapeutic procedures NEC</i>		
Drug titration	1	0
Surgery	1	0
Therapy interrupted	1	0
Surgical & medical procedures SOC TOTAL	3	0

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Reaction Name	Total	Fatal
Vascular disorders		
<i>Aortic necrosis and vascular insufficiency</i>		
Aortic arteriosclerosis	1	0
<i>Circulatory collapse and shock</i>		
Circulatory collapse	11	0
<i>Haemorrhages NEC</i>		
Haemorrhage	3	0
<i>Peripheral vascular disorders NEC</i>		
Cyanosis	1	0
Flushing	10	0
Hot flush	2	0
<i>Peripheral vasoconstriction, necrosis and vascular insufficiency</i>		
Peripheral coldness	1	0
<i>Site specific vascular disorders NEC</i>		
Pallor	9	0
<i>Vascular hypertensive disorders NEC</i>		
Hypertension	3	0
<i>Vascular hypotensive disorders</i>		
Hypotension	10	0
<i>Vasculitides NEC</i>		
Vasculitis	1	0
Vascular disorders SOC TOTAL	52	0
TOTAL REACTIONS FOR DRUG	3545	96
TOTAL REPORTS	1512	
TOTAL FATAL OUTCOME REPORTS		96